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510(k) SUMMARY

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DEVICE NAME: Ortho-mune™ OK-COMBO CD3-FITC/CD4-PE (OKT™3/OKT4A) Monoclonal Antibody (Murine)

PREDICATE: Simultest™ CD3/CD4 (Leu™-4/3a)

DATE: February 3, 1995

DEVICE DESCRIPTION:

Ortho-mune OK-COMBO CD3-FITC/CD4-PE (OKT3/OKT4A) Monoclonal Antibody (Murine) is a blend of the individual purified monoclonal antibodies OKT3 and OKT4A conjugated to the fluorochromes fluorescein isothiocyanate and phycoerythrin respectively.

INTENDED USE:

Ortho-mune OK-COMBO CD3-FITC/CD4-PE is intended for use in identification and enumeration of CD3+ and CD4+ human T lymphocytes in whole blood by flow cytometry. The intended use is the same as the intended use of the predicate device, Simultest CD3/CD4 (Leu-4/3a) commercially distributed by Becton Dickinson Immunocytometry Systems.

TECHNOLOGICAL CHARACTERISTICS:

Both Ortho-mune OK-COMBO CD3-FITC/CD4-PE (OKT3/OKT4A) Monoclonal Antibody (Murine) and Simultest CD3/CD4 (Leu-4/3a) utilize monoclonal antibodies specific for human T cells (OKT3/Leu-4) and human helper/inducer T cells (OKT4A/Leu-3a) respectively, conjugated to the same fluorochromes, fluorescein isothiocyanate and phycoerythrin.

PERFORMANCE DATA:

Performance of the two color reagent Ortho-mune OK-COMBO CD3-FITC/CD4-PE (OKT3/OKT4A) Monoclonal Antibody (Murine) was compared with that of Simultest CD3/CD4(Leu-4/3a). Whole blood specimens from 202 normal donors, and 86 AIDS/ARC patients were stained and analyzed using the CytoronAbsolute™ flow cytometer, Ortho Diagnostic Systems Inc.

For each specimen, the percentage of gated cells which showed positive staining by each marker was compared. The comparison was done by calculating the mean and range of the percent of positive stained cells for each marker. The Pearson product moment correlation was the statistical method used to compare the reagents. These data are shown in Table A for the normal population and in Table B for the AIDS/ARC population. OK-COMBO CD3-FITC/CD4-PE and Simultest CD3/CD4 reagents gave equivalent results for the CD3 and CD4 markers when used to stain whole blood from normal donors and AIDS/ARC patients.

TABLE A: N=202
PEARSON PRODUCT MOMENT CORRELATION
PERCENT POSITIVE STAINED CELLS IN NORMAL DONORS DETECTED BY OKT3/OKT4A AND LEU4/3a ASSAYED ON THE CYTORONABSOLUTE

Ortho-Mune Reagent	Mean%	Range%	BD Reagent	Mean%	Range%	Correlation	SL[1]
$OKT3^+$	75.8	58.3-89.1	$LEU4^+$	74.2	57.0-87.7	0.88	0.0001
$OKT4A^+$	46.2	13.5-69.0	$LEU3a^+$	45.3	14.5-64.1	0.93	0.0001
$OKT3^+T4A^+$	45.6	13.3-69.0	$LEU4^+3a^+$	44.9	14.3-63.7	0.93	0.0001

1. SL Is The Significance Level, e.g.. An SL Of 0.0500 Would Mean That There Is A 95% Probability That The Ortho-Mune And The BD Reagent Are Significantly Correlated.

TABLE B: N=86
PEARSON PRODUCT MOMENT CORRELATION
PERCENT POSITIVE STAINED CELLS IN AIDS/ARC DONORS DETECTED BY OKT3/OKT4A AND LEU4/3a ASSAYED ON THE CYTORONABSOLUTE

Ortho-Mune Reagent	Mean%	Range%	BD Reagent	Mean%	Range%	Correlation	SL[1]
$OKT3^+$	76.7	26.0-94.0	$LEU4^+$	76.5	39.8-95.3	0.90	0.0001
$OKT4A^+$	16.7	0.5-47.7	$LEU3a^+$	16.6	0.6-51.5	0.96	0.0001
$OKT3^+T4A^+$	16.2	0.4-47.5	$LEU4^+3a^+$	16.3	0.5-51.3	0.97	0.0001

1. SL Is The Significance Level, e.g. An SL Of 0.0500 Would Mean That There Is A 95% Probability That The Ortho-Mune And The BD Reagent Are Significantly Correlated.

Studies were also performed using the Becton Dickinson FACScan™ flow cytometer. Whole blood samples were collected from 17 normal donors. These samples were tested as collected to provide normal range cell counts, and were also concentrated 5-fold and diluted 5-fold to yield high range and low range cell counts. Samples were stained using Ortho-mune OK-COMBO CD3-FITC/CD4 PE and Simultest CD3/CD4 (Lev-4/3A) reagent. The samples stained with the OK-COMBO reagent were analyzed on both the CytoronAbsolute flow cytometer and the FACScan flow cytometer. The same samples stained with Simultest reagent were analyzed on the FACScan flow cytometer.

The mean percentage and range of positive stained cells for each marker and for the double positive stained cells were correlated using Pearson product moment correlation. The results with Ortho-mune OK-COMBO reagent analyzed on both the CytoronAbsolute flow cytometer and the FACScan flow cytometer are provided in Table F. The results comparing the OK-COMBO reagent with the Simultest reagent analyzed on the FACScan flow cytometer are provided in Table G.

The data demonstrate equivalent performance of Ortho-mune OK-COMBO CD3-FITC/CD4-PE reagent using both the CytoronAbsolute and FACScan flow cytometers, and equivalent performance of Ortho-mune OK-COMBO CD3-FITC/CD4-PE reagent to the Simultest CD3/CD4 (Leu-4/3a) reagent when analyzed on the FACScan flow cytometer.

TABLE F: N=50
OKT3/OKT4A ASSAYED ON FACSCAN AND CYTORON

Ortho-Mune Reagent	FACScan		Cytoron		FACScan Vs Cytoron	
	Mean%	Range	Mean%	Range	Correlation	SL[1]
$OKT3^+$	72.7	53.0-92.0	72.3	51.9-84.9	0.82	0.0001
$OKT4A^+$	52.6	39.0-65.0	49.2	34.7-62.7	0.89	0.0001
$OKT3^+T4A^+$	49.0	35.0-68.0	48.4	34.0-62.4	0.89	0.0001

1. SL Is The Significance Level, e.g. SL Of 0.0500 Would Mean That There Is A 95% Probability That The Ortho-Mune Reagent, Assayed On Both Instruments, Are significantly Correlated.

TABLE G: N=50 OKT3/OKT4A VS LEU4/3a ASSAYED ON THE FACSCAN							
Ortho-Mune Reagent	FACScan		**BD Reagent**	FACScan		Ortho Vs BD Reagent	
	Mean%	Range		Mean%	Range	Correlation	SL[1]
$OKT3^+$	72.7	53.0-92.0	$LEU4^+$	71.8	52.0-88.0	0.85	0.0001
$OKT4A^+$	52.6	39.0-65.0	$LEU3a^+$	51.8	36.0-65.0	0.92	0.0001
$OKT3^+T4A^+$	49.0	35.0-68.0	$LEU4^+3a^+$	47.5	33.0-62.0	0.91	0.0001

1. SL Is The Significance Level, e.g. SL Of 0.0500 Would Mean That There Is A 95% Probability That The Ortho-Mune And BD Reagents, Assayed On The FACScan, Are Significantly Correlated.

CONCLUSIONS:

1. Performance of the two color reagent Ortho-mune OK-COMBO CD3-FITC/CD4PE (OKT3/OKT4A) Monoclonal Antibody (Murine) is substantially equivalent to Simultest CD3/CD4 (Leu-4/3a) reagent in identification and enumeration of CD3+ and CD4+ human lymphocytes in whole blood by flow cytometry.